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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,334	06/19/2001	Sylvain Chemtob	2861-4003	9475

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/29/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/787,334

Applicant(s)

CHEMTOB ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears n the cover she t with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 19 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 7/18/01, has been entered into the record.
- B. Claims 1-9 were pending in the application and were subject to restriction in Paper No. 9, dated 8/19/02. In Paper No. 10, filed 9/19/02, Applicants elected Group I, claims 1-3, 5 and 8 as drawn to SEQ ID NO:1. Applicants argue that claims 3 and 8 as well as 4 and 9 are related by the fact that the claimed antagonists inhibit uterine contraction, which is the inventive concept. Applicants also argue that searching all 12 SEQ ID Nos would not be a serious burden on the Examiner. Upon consideration, the Examiner has agreed to combine Groups I and II and to examine claims 1-5, 8 and 9 and to search all SEQ ID Nos which have the same basic structure as SEQ ID NO:1 (i.e. only differ by a single residue). Therefore, claims 1-5, 8 and 9 will be examined insofar as they read on SEQ ID NO:1 and 4-11. This restriction is deemed proper and is, therefore, made FINAL.

2. Information Disclosure Statement

- A. The International Search Report citation has been lined through since this report is not proper subject matter for a Form PTO-1449.

3. Specification

- A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title recites that the claimed invention is drawn toward agonists. However, the claims are drawn only to antagonists.
- B. The specification is objected to since no priority information, including reference to application 09/154,627 (now abandoned) is recited in the first line of the specification. Priority to 09.154,627 is recited in the Oath/Declaration.
- C. Figure 2a is objected to since there is no reference to the term "PCP-8." In other words, no data is represented by the term "PCP-8," whereas the Brief Description of Figures references "PCP-8."

4. Claim Objections

A. Claim 1 is objected to since it recites "a G protein-coupled receptor antagonist of claim 3." It is believed that claim 1 should be an independent claim, especially given that claim 3, itself, depends from claim 1.

B. Claims 1-5, 8 and 9 are objected to since they recite, or depend from claims which recite, non-elected SEQ ID NO2. This non-elected subject matter should be removed from the claims.

C. The syntax of claim 5 can be improved by amending the phrase :a G protein-coupled receptor an antagonist."

6. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite "the use of," which is non-statutory language. The claims should be amended to recite, for example, "the method of..."

7. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-5, 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 2, 4 and 5 of U.S. Patent No. 6,300,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent is a genus claim. It recites "a prostaglandin receptor antagonist

which binds to an intracellular molecular interface formed by said prostaglandin receptor and a G-protein, wherein said antagonist is a peptide fragment of said prostaglandin receptor obtained from the third or fourth intracellular domain of the prostaglandin receptor.” The peptides of claim 1 of the application are species of the peptides claimed in the patent. Similarly, the methods of using the peptides of the application use species from the genus claimed in the patent.

8. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1, 3-5, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptides of SEQ ID NO:1 and 4-11, does not reasonably provide enablement for proteins which are “functional peptide analogs” of these SEQ ID NOs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all G protein-coupled receptor antagonists which are “functional peptide variants” of SEQ ID NO:2. These proteins would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:1 or 4-11. Other than SEQ ID NO:1 and 4-11, which appear to be derivatives of each other, or at least of SEQ ID NO:1, by the substitution of one amino acid, Applicants provide no guidance or working examples of functional derivatives, nor do they provide any guidance as to what residues are critical for peptide *function*. Applicants define “functional derivatives” as “any mimetic compounds and/or structurally unrelated compounds.” Therefore, any compound, including those with entirely different structures, such as synthetic non-peptidic organic compounds and other small molecules, would be included in the scope of these claims. It is not predictable to one of ordinary skill in the art how to make a functional

derivative other than those of SEQ ID NO:1 and 4-11, especially since these derivatives may have no amino acid structure in common with these SEQ ID NOs, or may not have amino acids at all.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all functional derivatives of SEQ ID NO:1 or 4-11. There is also a lack of guidance and working examples of these derivatives, including which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make functional derivatives of SEQ ID NO:1 and 4-11, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

9. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1, 3-5, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the term "G protein-coupled receptor antagonist" is confusing since it is not clear if this is referring to an antagonist to a G protein-coupled receptor, or to a full-length G protein-coupled receptor which is, itself, an antagonist. As written, the claim reads on the full-length prostaglandin FP receptor, which comprises the claimed SEQ ID NOs. This receptor can be considered an antagonist since it could be used to bind to antibody specific for said receptor, thereby acting as an antagonist to the antibody. If this is the case, then an art rejection under 35 USC 102 will be made over the full-length FP receptor in the subsequent Office Action.

10. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

A. Claims 1-5, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Chemtob et al. (US Patent No. 6,300,312). The claims of the present invention recite G protein-coupled receptor antagonists of SEQ ID NO:1, 4-11, or functional derivatives thereof as well as methods of preventing premature delivery of a fetus. Claim 1 of the patent recites "a prostaglandin receptor antagonist which binds to an intracellular molecular interface formed by said prostaglandin receptor and a G-protein, wherein said antagonist is a peptide fragment of said prostaglandin receptor obtained from the third or fourth intracellular domain of the prostaglandin receptor." The claims of the patent also recite methods of using the peptides of the application use species from the genus claimed in the patent.

11. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 26, 2002

